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Oncology

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

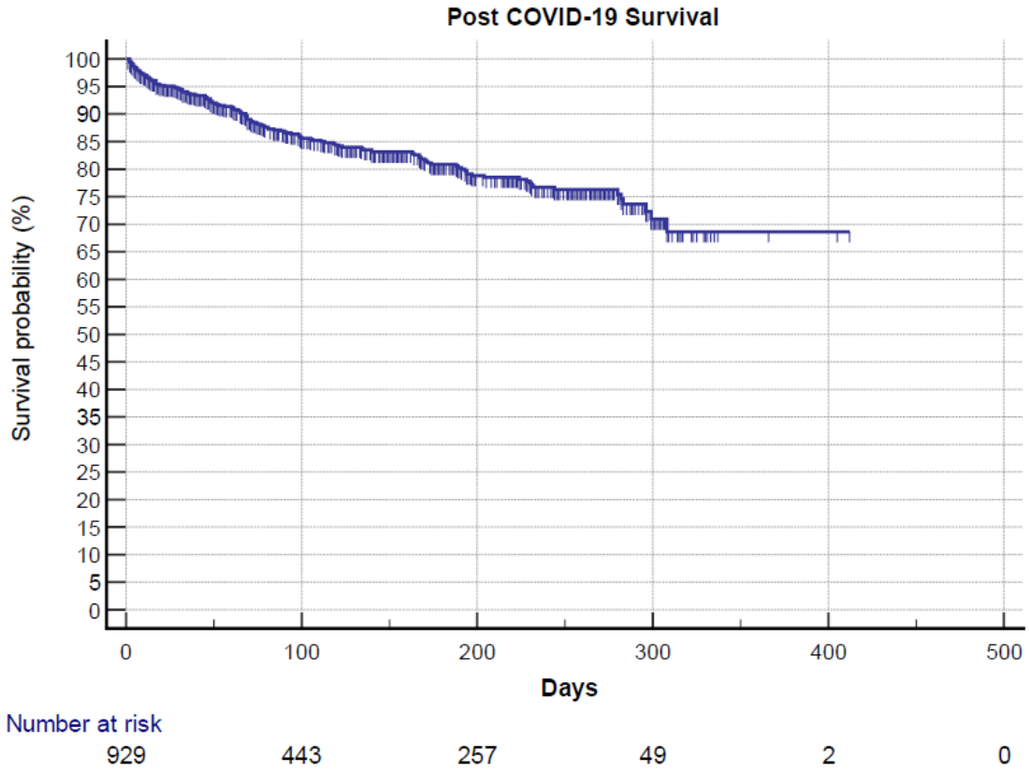
Supplement to: Pinato DJ, Tabernero J, Bower M, et al. Prevalence and impact of COVID-19 sequelae on treatment and survival of patients with cancer who recovered from SARS-CoV-2 infection: evidence from the OnCovid retrospective, multicentre registry study. *Lancet Oncol* 2021; published online Nov 3. http://dx.doi.org/10.1016/S1470-2045(21)00573-8.

Prevalence and impact of COVID-19 sequelae on treatment and survival of patients with cancer who recovered from SARS-Cov-2 infection: evidence from the OnCovid retrospective, multicentre registry study

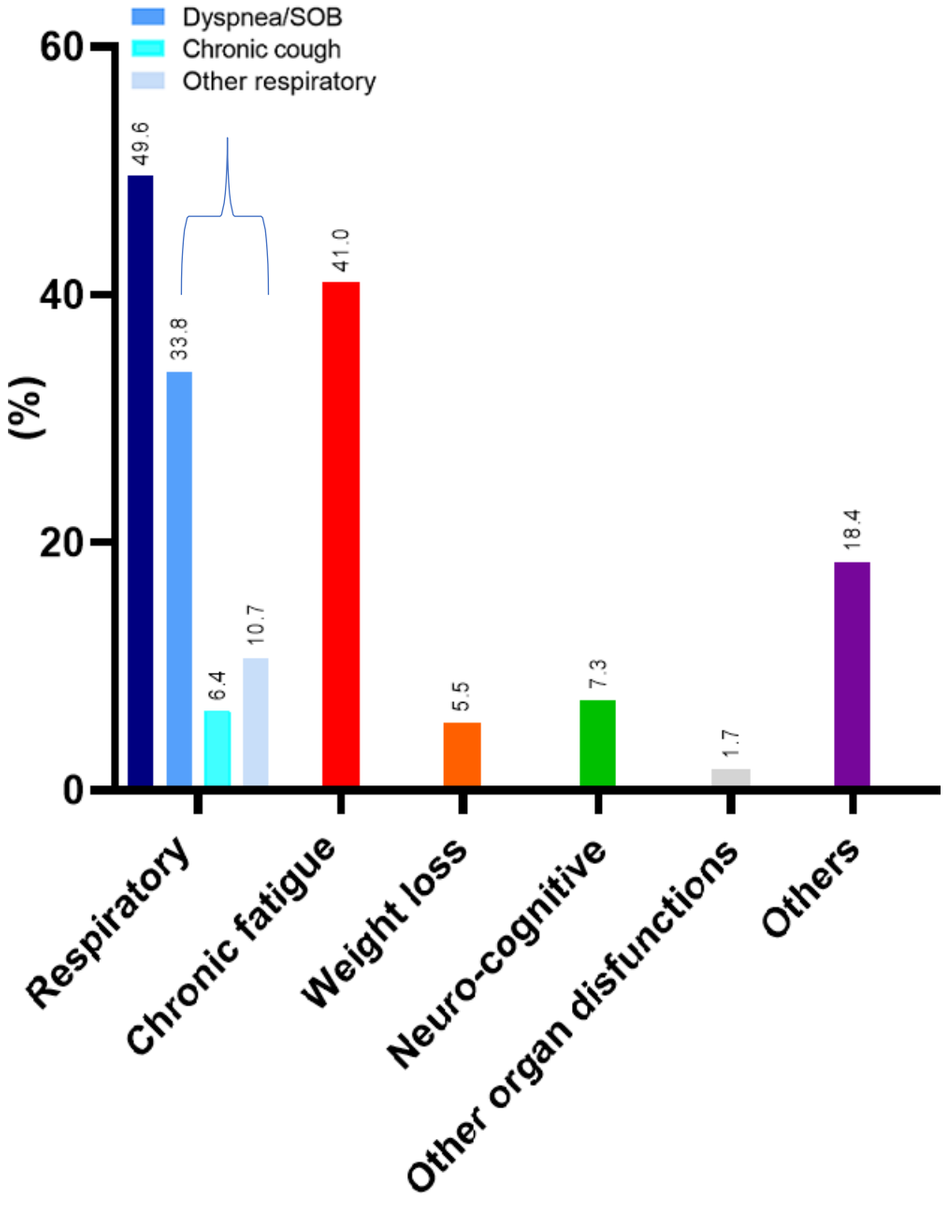
APPENDIX

CONTENTS

Supplementary Figure 1. Kaplan Meier survival estimate of post COVID-19 survival (days). The median post COVID-19 survival (929 patients) was not reached with 143 events

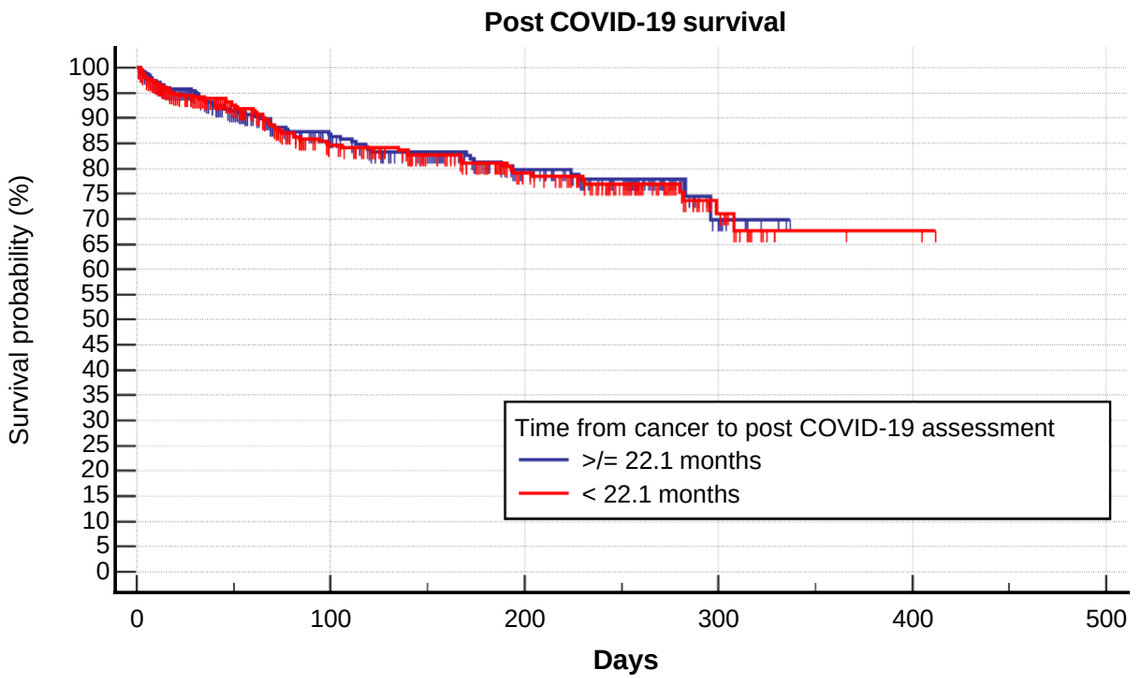


Supplementary Figure 2. COVID-19 sequelae. Overall 234 patients experienced at least 1 COVID-19 sequelae. Respiratory sequelae: 116 patients (49.6%), including chronic cough in 15 patients (6.4%), residual dyspnoea/shortness of breath in 79 patients (33.8%) and other respiratory sequelae in 25 patients (10.7%); chronic fatigue: 96 patients (41.0%); weight loss: 13 patients (5.5%), neuro-cognitive disfunctions (including dysgeusia/dysosmia): 17 patients (7.3%); non-respiratory organ disfunction: 4 patients (1.7%); others: 43 patients (18.4%).



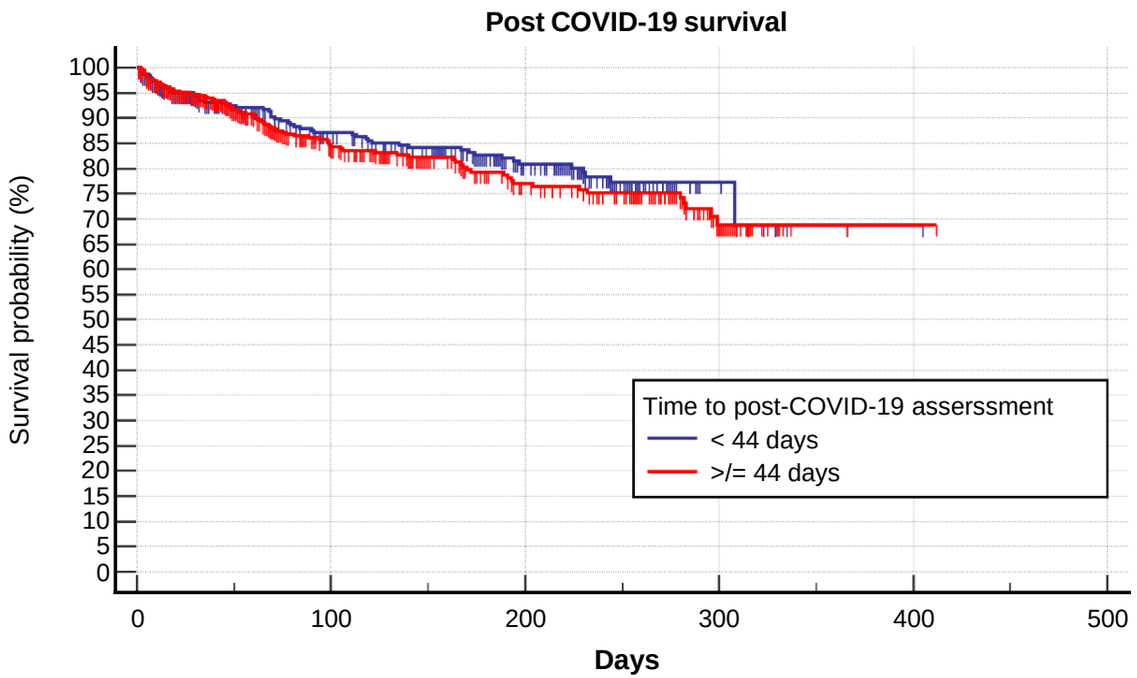
Supplementary Figure 3. A) Kaplan Meier survival estimate of post COVID-19 survival (days) according to the time from cancer diagnosis to post COVID-19 reassessment (not reached, 825 patients included (HR 1.03, 95%CI: 0.72-1.47; p=0.8570). **B)** Kaplan Meier survival estimate of post COVID-19 survival (days) according to the time from COVID-19 diagnosis to post COVID-19 reassessment. The median post COVID-19 survival (929 patients) was not reached with 143 events HR 1.13, 95%CI: 0.81-1.22; p=0.4431) (929 patients included

A



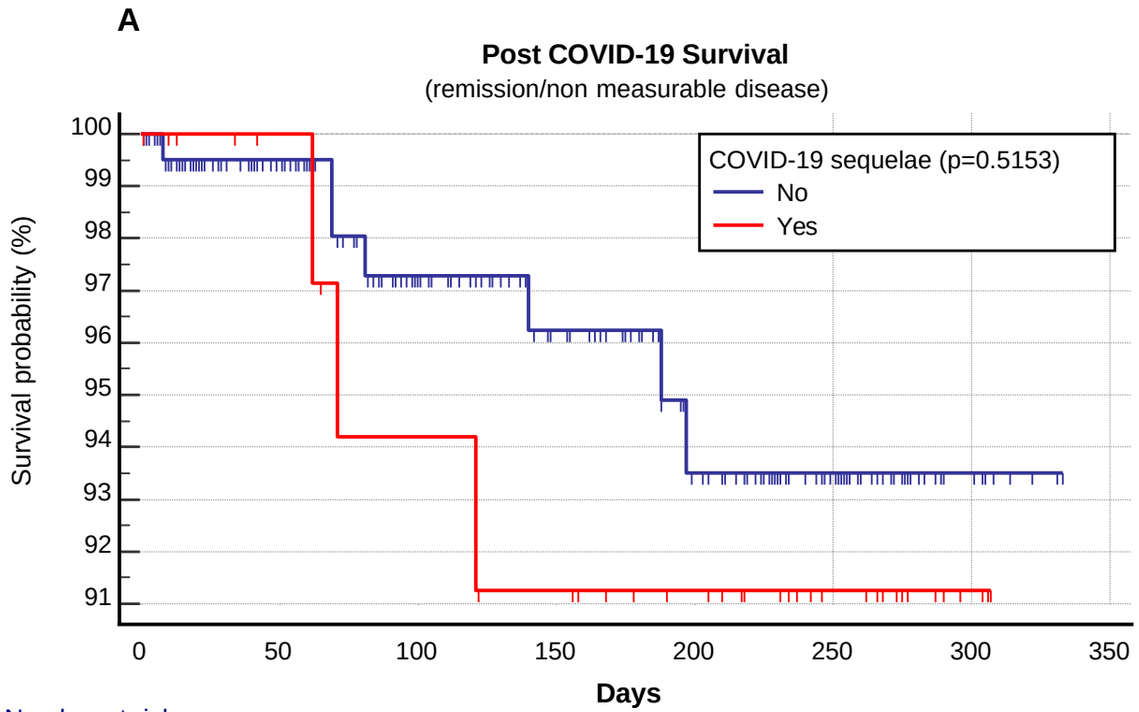
Number at risk					
>/= 22.1 months					
396	177	97	13	0	0
< 22.1 months					
429	199	119	27	2	0

B



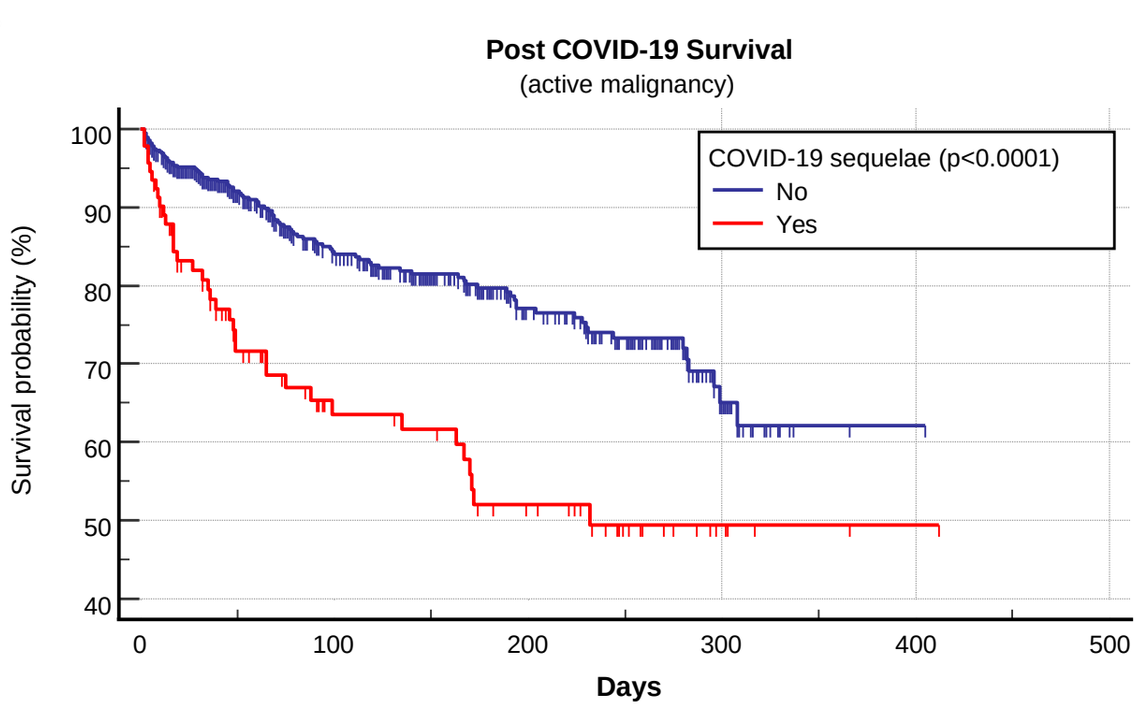
Number at risk					
< 44 days					
388	215	125	10	1	0
>/= 44 days					
541	228	132	39	1	0

Supplementary Figure 4. Kaplan Meier survival estimates. **A)** Post COVID-19 survival (days) in patients with remission/non measurable disease was not reached (10 events out of 261 evaluable patients – 3.8%) and COVID-19 sequelae did not impact post COVID-19 survival (HR 1.65, 95%CI: 0.36-7.49; p=0.5153).
B) Post COVID-19 survival (days) in patients with active disease overall was not reached (130 events out of 654 evaluable patients – 19.9%). COVID-19 sequelae significantly impacted post COVID-19 survival (HR 3.32, 95%CI: 2.01-5.48; p<0.0001).



Number at risk

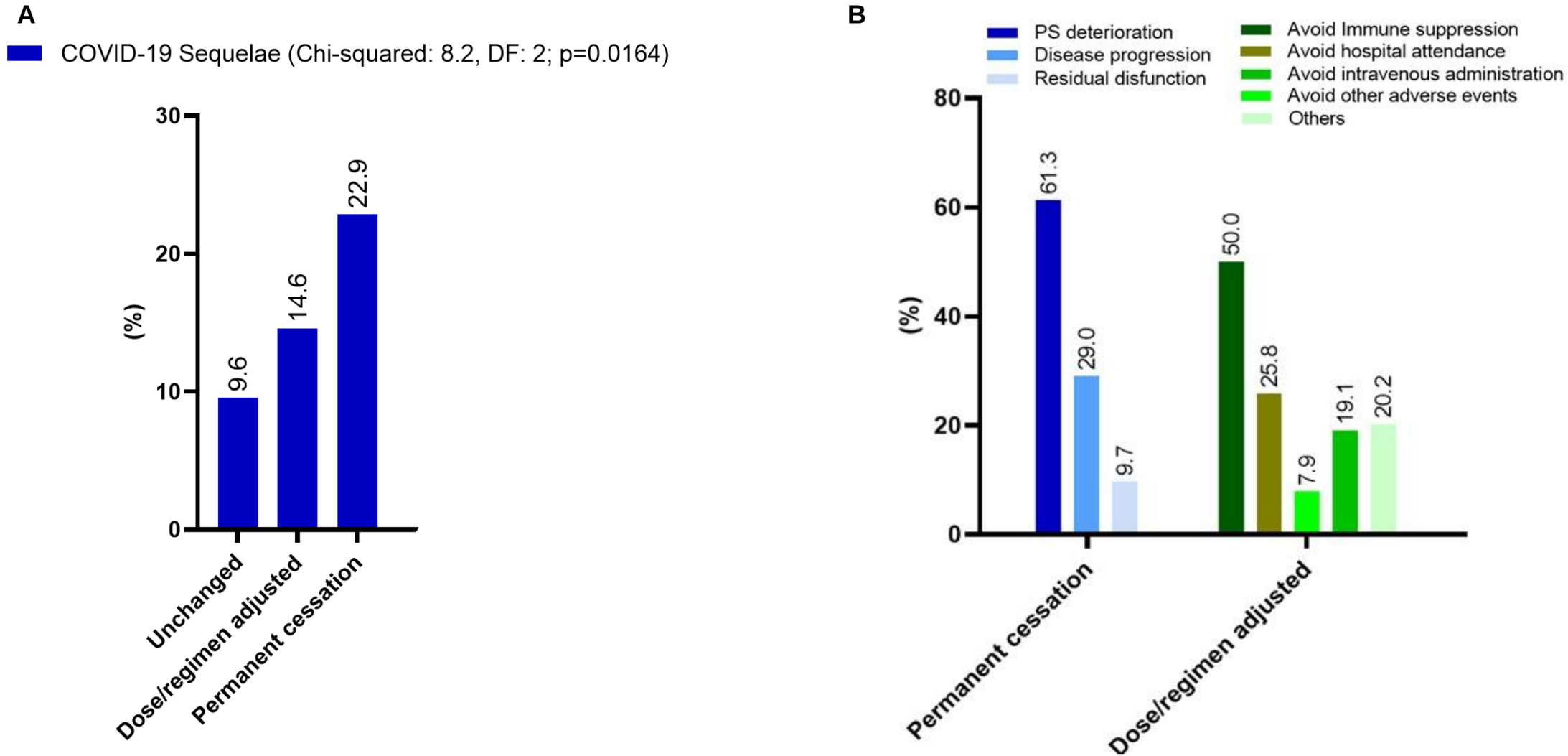
No	219	156	112	89	66	38	11	0
Yes	42	35	32	30	24	14	3	0



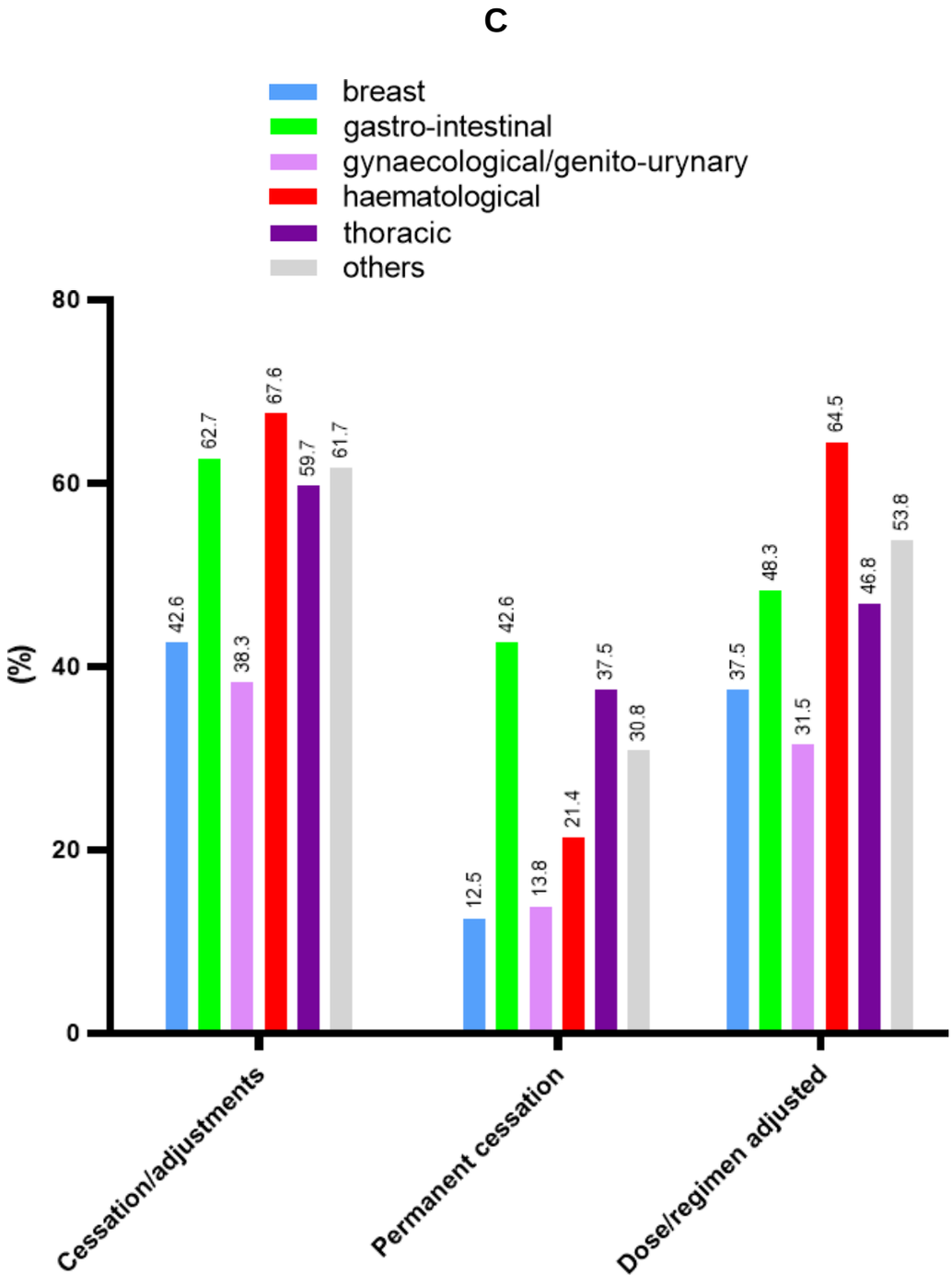
Number at risk

No	562	254	138	30	1	0
Yes	92	35	24	5	1	0

Supplementary Figure 5. A) Detailed underlying causes for SACT permanent cessation (70 patients) and regimen adjustments (178 patients).
Reason to permanent discontinuation (31 patients): 19 (61.3%) performance status (PS) deterioration, 9 (29%) disease progression during COVID-19, 3 (9.7%) residual organ disfunction. Dose/regimen adjustments: 89 (50%) avoid potential immune suppression, 46 (25.8%) avoid hospital attendance, 14 (7.9%), avoid intravenous administration, 34 (19.1%) avoid other adverse events, 36 (20.2%) other reasons. **B)** Histogram reporting the paired prevalence of COVID-19 sequelae according to post COVID-19 SACT resumption pathways (the Pearson χ2 test was used). COVID-19 sequelae (yes vs no): SACT unchanged: 21/218 (9.6%), dose/regimen adjusted: 26/178 (14.6%), permanent cessation: 16/70 (22.9%).



Supplementary Figure 5C. Histogram with paired prevalence of SACT permanent cessation and dose/regimen adjustments according to the primary tumour category.
Permanent cessation plus dose/regimen adjustments: breast 52/122 (42.6%), gastro-intestinal 52/83 (62.7%), genaecological/genito-urinary 31/81 (38.3%), haematological 46/68 (67.6%), thoracic 37/62 (59.7%), others 29/47 (61.7%). Chi-sqared: 23.8, DF: 5; p=0.0002.
Permanent cessation (dose/regimen adjustments excluded): breast 10/80 (12.5%), gastro-intestinal 23/54 (42.6%), genaecological/genito-urinary 8/58 (13.8%), haematological 6/28 (21.4%), thoracic 15/40 (37.5%), others 8/26 (30.8%). Chi-sqared: 23.7, DF: 5; p=0.0002.
Dose regimen adjustments (permanent cessation excluded): breast 42/112 (37.5%), gastro-intestinal 29/60 (48.3%), genaecological/genito-urinary 23/73 (31.5%), haematological 40/62 (64.5%), thoracic 22/47 (46.8%), others 21/39 (53.8%). Chi-sqared: 19.0, DF: 5; p=0.0019.



Supplementary Table 1: Detailed comorbidities.

Comorbidities	
Ischaemic heart disease	79 (7.8)
Dementia	33 (3.3)
Diabetes	183 (18.0)
Immunosuppression	23 (2.3)
Congestive cardiac failure	14 (1.4)
Liver impairment	14 (1.4)
Hypertension	420 (41.4)
Peripheral vascular disease	29 (2.9)
Cardiovascular disease	110 (10.8)
Cerebro-vascular disease	44 (4.3)
Chronic pulmonary disease	120 (12.99)
Chronic kidney disease	58 (5.7)
Obesity (BMI > 30)	29 (2.9)
Others	249 (24.5)

Supplementary Methods

OnCovid (NCT04393974) is an active European registry study that, since the beginning of the pandemic, has collected consecutive patients fulfilling the following inclusion criteria: 1) age ≥18 years; 2) diagnosis of SARS-CoV-2 infection confirmed by RT-PCR of a nasopharyngeal swab; 3) history of solid or hematologic malignancy, at any time during the patients' past medical history, either active or in remission at the time of COVID-19 diagnosis. Patients with a history of non-invasive/premalignant lesions or with low malignant potential (i.e., basal cell carcinoma of the skin, non-invasive carcinoma in situ of the cervix, ductal carcinoma in situ) were excluded. For hematologic malignancies, only patients with a history of oncologic diseases with defined malignant behavior (lymphoma, leukaemia, multiple myeloma) were included.
OnCovid was granted central approval by the United Kingdom Health Research Authority (20/HRA/1608) and by the corresponding research ethics committees at each participating institution. Core study data were collated from electronic medical records into a case report form designed using the Research Electronic Data Capture software (REDCap, Vanderbilt University, Nashville, TN, USA). Multi-site access and data curation was coordinated by the Medical Statistics Unit in Novara, Italy.
This OnCovid registry focused on post COVID-19 outcomes among COVID-19 survivors who underwent a formal clinical reassessment at the participating institutions.
COVID-19 sequelae were defined as any residual symptoms and/or measurable organ disfunction attributable to COVID-19 according to investigators. Patterns of SACT resumption were assessed among patients who were on systemic anti-cancer therapy (SACT) within 4 weeks of COVID-19 diagnosis.
Accounting for the unbalanced distribution of patient/disease-related features across the subgroups we adopted a fixed multivariable regression model, adjusting all survival estimates for clinical characteristics already known to influence clinical outcomes in patients with COVID-19 and cancer. Included covariates were incorporated following a clinical prioritization. In addition, all of them revealed to be associated with both the short-term and medium-term outcomes at the latest updated of the registry including 1392 patients (Pinato DJ, et al. Eur J of Cancer 2021).

The following key variables of interest were used as covariates within the survival analysis:
- Gender (male vs female),
- Age (≥65 vs < 65 years),
- Number of co-morbidities (0-1 vs ≥ 2),
- Primary tumour (clustered as: breast, gastro-intestinal, gynaecological/genito-urinary, haematological, thoracic, and others),
- Tumour stage (defined as advanced vs non-advanced). In details, we defined as “advanced” stage any patient with distant metastatic disease, to differentiate them from “non-advanced” patients. Disease-specific criteria (i.e. Rai, Binet criteria etc.) were utilised as appropriate to define advanced haematological malignancies.
- Tumour status (presence of active vs non-active disease), on the basis of disease-specific criteria (radiologic, clinical, biochemical/haematological depending on disease type).

- Receipt of any anticancer therapy within 4 weeks of SARS-CoV-2 infection, including non-systemic therapy (yes vs no),
- Experience of at least one COVID-19 complications including acute respiratory failure, ARDS, kidney injury, secondary infections, sepsis, septic shock, acute cardiac injury, acute liver injury and others (yes vs no);
- Receipt of any COVID-19 specific therapy, including antivirals, antimalarials, antibiotics, corticosteroids and others (yes vs no),
- Hospitalization requirement (pre-existent/due to COVID-19 vs not required).

In order to provide an estimate of COVID-19 sequelae distribution across different age-groups and to account for their possible relationship with COVID-19 severity, we described sequalae proportion, rate of complicated COVID-19 and hospital admission due to COVID-19, according to 6 age-categories: <40 years old, 40-49 years old, 50-59 years old, 60-69 years old, 70-79 years old, ≥ 80 years old.
Being an observational study, decisions on initiating, resuming or discontinuing therapy were dictated by the discretion of the treating clinicians. The overarching subgrouping of tumour related features according to stage, activity and therapy has been consistently utilised in all the publications from our registry (Cancer Discov. 2020 Jul 31;10(10):1465–74, Eur J Cancer. 2021 Jun;150:190-202, J Immunother Cancer. 2021 Mar;9(3):e002277, Cancers. 2020 Jul 8;12(7):1841) and was made necessary by the wide heterogeneity oncological diagnoses included in the registry.
Additional variables reported in the descriptive analysis were: smoking history (former/current smokers vs never smokers), systemic anticancer therapy (chemotherapy, immune checkpoint inhibitors, other targeted agents and endocrine therapy), median time (in days) from symptoms to SARS-CoV-2 infection diagnosis, COVID-19 therapy details (antibiotics, antimalarials, antivirals, IL-6 inhibitors, corticosteroids and others), intensive care admission, mechanical ventilation requirements, and oxygen therapy.
Oncological and disease specific variables were collected at baseline, defined at the moment of diagnosis of SARS-Cov-2 by PCR test. Characteristics of severity, complications and therapy against COVID-19 were collected throughout the observation period until full clinical resolution of COVID-19 or patients' mortality.
Patient observation time started from date of first PCR/SARS-CoV-2 infection confirmation until patient death or loss to follow-up. Being a retrospective, observational study, the entirety of the OnCovid cohort was followed up at intervals dictated by the routine clinical practice in each participating institutions, as deemed clinically indicated by the treating physicians. All-cause of mortality was retrieved and validated by investigators at each centre by accessing patients' electronic medical records and death certificates.
Patients were lost to follow-up when for any reason failed to attend planned follow-up appointments scheduled by the treating clinicians. Given the pragmatic nature of this registry, based on standard of care clinical practice, we could not accurately reconstruct the reasons to explain why a proportion of patients did not attend for follow-up. To avoid incurring into bias, by mislabelling patients that were lost to follow-up as potentially deceased, we decided to exclude all patients with incomplete/missing follow up data to preserve the integrity of our results.
We also performed an ancillary analysis evaluating post COVID-19 anti-SARS-CoV-2-S (Spike) IgG seroprevalence. To define patient/disease characteristics possibly related to seroconversion, their distribution according to the antibody status were described. Serum SARS-CoV-2 antibodies were tested in clinical practice at participating institution and seroconversion has been defined as the presence of positive anti-SARS-CoV-2-S (Spike) IgG antibody test after COVID-19 resolution.

Supplementary Table 2: Patient disposition across participating centres. PI: principal investigator.

Institution	Patients		Site PI
	N	%	
Chelsea and Westminster Hospital, London (UK)	361	13.7%	Mark Bower
Vall d'Hebron University Hospital, Barcelona (Spain)	294	11.2%	Josep Tabernero
University College London, London (UK)	209	7.9%	Diego Ottaviani
Ospedale Maggiore della Carità, Novara (Italy)	207	7.9%	Alessandra Gennari
Institut Gustave Roussy, Villejuif (France)	187	7.1%	Emeline Colomba
Guy's and St Thomas' NHS Foundation Trust, London (UK)	150	5.7%	Saoirse Dolly
Barts Health NHS Trust, London (UK)	145	5.5%	Nikolaos Diamantis
Humanitas Cancer Centre, Milan (Italy)	139	5.3%	Alexia Bertuzzi
ICO L'Hospitalet, L'Hospitalet de Llobregat, Barcelona (Spain)	123	4.7%	Ramon Salazar
Ospedale Papa Giovanni XXIII, Bergamo (Italy)	107	4.1%	Alberto Zambelli
Policlinico San Matteo, Pavia (Italy)	67	2.5%	Gianpiero Rizzo
ICO Badalona (Spain)	61	2.3%	Eudald Felip
IRCCS AOU San Martino, Genova (Italy)	56	2.2%	Matteo Lambertini
ICO Girona (Spain)	56	2.1%	Joan Brunet
Hospital Clinic, Barcelona (Spain)	53	2.0%	Aleix Prat
Ospedale Antonio e Biagio e Cesare Arrigo, Alessandria (Italy)	53	2.0%	Antonio Maconi
Imperial College London, London (UK)	46	1.7%	David J Pinato
Velindre Cancer Centre, Cardiff (UK)	34	1.3%	John Chester
Manresa (Spain)	33	1.3%	Clara Martinez-Vila
Institut Jules Bordet, Brussels (Belgium)	30	1.1%	Angela Loizidou
University of L'Aquila, L'Aquila (Italy)	30	1.1%	Corrado Ficorella
Azienda Ospedaliera Spedali Civili, Brescia (Italy)	26	1.0%	Salvatore Grisanti
Azienda Istituti Ospitalieri di Cremona, Cremona (Italy)	25	0.9%	Daniele Generali
Università Campus Bio-Medico, Rome (Italy)	20	0.8%	Buno Vincenzi
University of Munich (Germany)	19	0.7%	Nadia Harbeck
Hospital Universitario 12 de Octubre, Madrid (Spain)	15	0.6%	Ana Sanchez de Torre
Azienda Ospedaliera S Maria, Terni (Italy)	14	0.5%	Annalisa Guida
Ospedali Riuniti di Ancona, Universitá Politecnica delle Marche (Italy)	14	0.5%	Rossana Berardi
Istituto Europeo di Oncologia, Milano (Italy)	10	0.4%	Paola Queirolo
Fondazione Poliambulanza Istituto Ospedaliero, Brescia (Italy)	10	0.4%	Michela Libertini
Istituto Tumori, Milan (Italy)	8	0.3%	Rossella Bertulli
Careggi University Hospital, Florence (Italy)	8	0.3%	Francesca Mazzoni
Santa Maria Goretti Hospital, Latina (Italy)	8	0.3%	Federica Zoratto
Azienda Ospedaliera S. Andrea, Rome (Italy)	8	0.3%	Raffaele Giusti
Palma de Mallorca Hospital, Palma de Mallorca, (Spain)	4	0.2%	Maria Iglesias
University of Bari 'Aldo Moro', Bari (Italy)	4	0.2%	Marco Tucci
Total	**2634**	**100.0%**	

Supplementary Table 3: Distribution of baseline patients, tumour and COVID-19 characteristics among the overall entered population and among patients who underwent a formal clinical re-assessment at participating institutions.

Characteristic	Overall Population	Post-COVID-19 analysis
	N = 2634 (%)	N = 1557 (%)
Sex		
Male	1390 (52.8)	751 (48.3)
Females	1240 (47.2)	803 (51.7)
Missing	4	3
Age		
<65 years	1083 (41.3)	788 (50.8)
≥65 years	1538 (58.7)	763 (49.2)
Missing	13	6
Comorbidities		
0-1	1414 (53.7)	962 (61.8)
≥2	1220 (46.3)	595 (38.2)
Smoking history		
Never smokers	1128 (51.9)	732 (55.7)
Former/current smokers	1044 (48.1)	583 (44.3)
Missing	462	242
Primary Tumour		
Breast	493 (18.9)	360 (23.4)
Gastrointestinal	476 (18.2)	255 (16.5)
Gynaecological/Genito-Urinary	530 (20.3)	297 (19.3)
Haematological	357 (13.7)	218 (14.1)
Thoracic	375 (14.4)	188 (12.2)
Others	382 (14.6)	223 (14.5)
Missing	21	16
Tumour stage		
Local/loco-regional	1237 (53.96)	741 (50.7)
Advanced	1244 (46.04)	720 (49.3)
Missing	153	96
Tumour status at COVID-19 diagnosis		
Remission/non measurable disease	860 (33.3)	520 (33.9)
Active malignancy	1723 (66.7)	1015 (66.1)
Missing	51	22
Anticancer therapy at COVID-19 diagnosis		
No	1213 (48.2)	819 (54.5)
Yes	1305 (51.8)	685 (45.5)
Missing	116	53
COVID-19 therapy		
No	1129 (42.9)	707 (45.4)
Yes	1505 (57.1)	850 (54.6)
Antibiotics	1242 (47.1)	650 (41.7)
Antimalarials	615 (23.3)	394 (25.3)
Antiviral	400 (15.2)	231 (14.8)
IL-6 Inhibitors	93 (3.5)	59 (3.8)
Corticosteroids	489 (18.6)	248 (15.9)
Other	162 (6.2)	104 (6.7)
Complicated COVID-19		
No	1554 (59.0)	1154 (74.1)
Yes	1080 (41.0)	403 (25.9)
Hospitalization		
Not required	593 (22.7)	519 (33.5)
Required	1387 (53.1)	711 (45.9)
Pre-existing	633 (24.2)	318 (20.5)
Missing	21	9
Intensive care admission		
No	1649 (84.5)	880 (87.7)
Yes	273 (14.0)	117 (11.7)
Indicated but not admitted	30 (1.5)	6 (0.6)
Missing	682	554
Mechanical ventilation		
No	2117 (88.6)	1343 (93.9)
Yes	273 (11.4)	87 (6.1)
Missing	244	127
Oxygen therapy		
No	1208 (48.7)	930 (62.8)
Yes	1272 (51.3)	551 (37.2)
Missing	154	76

Supplementary Table 4: Fixed multivariable regression model for post COVID-19 survival including patients on SACT at COVID-19 diagnosis (309 patients included). HR: hazard ratio; CI: confidence interval.

Oncology therapeutic pathway	Multivariable analysis
	HR 95%CI; p-value
SACT	
Unchanged	1
Dose/regimen adjusted	0.84 (0.35-2.02)
Permanent cessation	3.53 (1.45-8.59)
Sex	
Female	1
Male	0.72 (0.34-1.50)
Age	
<65 years	1
≥65 years	1.27 (0.64-2.52)
Comorbidities	
0-1	1
≥2	1.46 (0.71-3.03)
Primary tumour	
Breast	2.09 (0.31-14.07)
Gastrointestinal	3.94 (0.80-19.30)
Gynaecological/Genito-Urinary	3.79 (0.72-19.86)
Thoracic	3.27 (0.60-17.79)
Other	6.15 (1.19-31.65)
Haematological	1
Tumour stage	
Local/loco-regional	1
Advanced	2.49 (0.90-6.86)
Tumour status	
Remission/non measurable disease	1
Active malignancy	7.12 (0.90-56.33)
COVID-19 complications	
0	1
≥1	2.92 (1.25-6.78)
COVID-19 therapy	
No	1
Yes	0.71 (0.35-1.45)
Hospitalization	
Not- Required	1
Required due to COVID-19	1.27 (0.40-4.06)
Pre-existing	3.27 (1.03-10.38)
COVID-19 sequelae	
No	1
Yes	1.21 (0.51-2.88)

Supplementary Table 5: Distribution of baseline patients, tumour and COVID-19 characteristics according to the post COVID-19 SARS-CoV-2 antibody status. *Within 4 weeks of COVID-19 diagnosis.

	Negative SARS-CoV-2 antibodies	Positive SARS-CoV-2 antibodies	P value
	N = 32 (%)	N = 318 (%)	
Sex			
Male	10 (31.2)	141 (44.3)	0.15
Females	22 (68.7)	177 (55.7)	
Age			
<65 years	19 (59.4)	176 (55.5)	0.67
≥65 years	13 (40.6)	141 (44.5)	
Comorbidities			
0-1	24 (75.0)	210 (66.0)	0.31
≥2	8 (25)	108 (34.0)	
Smoking history			
Never smokers	20 (71.4)	163 (58.6)	0.18
Former/current smokers	8 (28.6)	115 (41.4)	
Missing	4	40	
Primary Tumour			
Breast	9 (28.1)	106 (33.7)	0.35
Gastrointestinal	3 (9.4)	42 (13.3)	
Gynaecological/Genito-Urinary	8 (25.0)	44 (14.0)	
Haematological	8 (25.0)	57 (18.1)	
Thoracic	3 (9.4)	31 (9.8)	
Others	1 (3.1)	35 (11.1)	
Missing	0	3	
Tumour stage			
Local/loco-regional	14 (46.7)	138 (46.8)	0.99
Advanced	16 (53.3)	157 (53.2)	
Missing	2	23	
Tumour status at COVID-19 diagnosis			
Remission/non measurable disease	9 (29.0)	116 (37.2)	0.36
Active malignancy	22 (71.0)	196 (62.8)	
Missing	1	6	
Anticancer therapy at COVID-19 diagnosis*			
No	22 (68.7)	191 (62.4)	0.48
Yes	10 (31.2)	115 (37.6)	
Missing	0	12	
COVID-19 therapy			
No	19 (59.4)	119 (37.4)	0.02
Yes	13 (40.6)	199 (62.6)	
Antibiotics	9 (28.1)	140 (44.0)	0.08
Antimalarials	9 (28.1)	115 (36.2)	0.36
Antiviral	4 (12.5)	84 (26.4)	0.08
IL-6 Inhibitors	2 (6.2)	19 (6.0)	0.95
Corticosteroids	5 (15.6)	62 (19.5)	0.59
Other	-	4 (1.3)	0.52
Complicated COVID-19			
0	26 (81.2)	238 (74.8)	0.42
≥ 1	6 (18.8)	80 (25.2)	
COVID-19 sequalae			
No	28 (87.5)	267 (84.0)	0.60
Yes	4 (12.5)	51 (16.0)	
Hospitalization			
Not required	15 (46.9)	100 (31.7)	0.21
Required	14 (43.7)	169 (53.7)	
Pre-existing	3 (9.4)	46 (14.6)	
Missing	0	3	

OnCovid Study group: Investigators

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Figure 2 Legend:

Histogram reporting the corresponding prevalence of COVID-19 sequelae, hospital admission due to COVID-19 and complicated COVID-19 across the 6 defined age categories. **Sequelae:** <40 yo: 8/112 (7.1%), 40-49 yo: 12/158 (7.6%), 50-59 yo: 45/334 (13.5%), 60-69 yo: 82/370 (22.2%), 70-79 yo: 63/396 (15.9%), ≥ 80 yo: 24/180 (13.3%). **Hospital admission (patients already hospitalized excluded):** <40 yo: 33/88 (37.6%), 40-49 yo: 51/125 (40.8%), 50-59 yo: 135/278 (48.5%), 60-69 yo: 191/302 (63.2%), 70-79 yo: 205/306 (66.9%), ≥ 80 yo: 95/126 (75.4%). **Complicated:** <40 yo: 11/112 (9.8%), 40-49 yo: 27/158 (17.1%), 50-59 yo: 68/334 (20.4%), 60-69 yo: 110/370 (29.7%), 70-79 yo: 128/396 (32.3%), ≥ 80 yo: 58/180 (32.2%). Linear trends were tested with the Cochran–Armitage test. Yo; years old.